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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,349	11/17/2003	Ellen L. Berg	SEEK-001CON	7039

24353 7590 10/24/2006

BOZICEVIC, FIELD & FRANCIS LLP
1900 UNIVERSITY AVENUE
SUITE 200
EAST PALO ALTO, CA 94303

EXAMINER

SKOWRONEK, KARLHEINZ R

ART UNIT PAPER NUMBER

1631

DATE MAILED: 10/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/716,349	Applicant(s) BERG ET AL.	
	Examiner Karlheinz R. Skowronek	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-22 is/are pending in the application.
- 4a) Of the above claim(s) 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17, and 19-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/27/04;10/18/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The examiner of record has changed. Please direct all further correspondence to Karlheinz R. Skowronek whose telephone number is (571) 272-9047.

Election/Restrictions

Applicant's election of specie B, Primary cells, in the reply filed on 24 July 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 18 October 2005 and 27 April 2004 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Claim Rejections - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "amount sufficient" in claim 17 is a relative term which renders the claim indefinite. The term "amount sufficient " is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. What is an amount sufficient to induce a plurality of pathways? Claims 19-22 are also rejected because they depend from claim 17, and thus contain the above issues due to said dependence.

Claim Rejections - 35 USC § 102

Claim 17 and 19-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Friend et al. (US PAT 6,801,859).

Claim 17 is directed to a method of analyzing a candidate compound for a biological activity of interest, comprising contacting a test cell culture with said compound, wherein said culture comprises a plurality of factors in an amount sufficient to induce a plurality of pathways; measuring at least two parameters associated with said plurality of pathways and comparing the measurement of said at least two parameters with the measurement from a control cell culture lacking said compound, and recording said measurements of said test cell culture and said control cell culture to produce a biological dataset profile, wherein said biological dataset profile is indicative of the pathways that are active in said cell culture.

Friend et al teach a method of analyzing a candidate compound for a biological activity of interest, comprising contacting a test cell culture with said compound (col.39

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line 28), wherein said culture comprises a plurality of factors in an amount sufficient to induce a plurality of pathways (col. 6, lines 43-46 and col. 52, lines 23-25); measuring at least two parameters associated with said plurality of pathways (col. 39, lines 32-33) and comparing (col. 39, lines 34-35) the measurement of said at least two parameters with the measurement from a control cell culture lacking said compound (col.39, line 31), and recording said measurements of said test cell culture and said control cell culture to produce a biological dataset profile (col. 16, lines 32-35), wherein said biological dataset profile is indicative of the pathways that are active in said cell culture.

Regarding claim 19, Friend et al. are silent on the limitation of primary cells, however teach that the method can be practiced with any cell type (col. 6, lines 31-32).

Regarding claim 20 and 21, Friend et al. teach the treatment of cells to increase or decrease in pathway activity (col. 52, line 19), which reads on treating with an inhibitor or activator of a pathway.

Regarding claim 22, Friend et al. teach the step of compiling a database of profiles (col. 24, lines 44-46).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

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F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Nonstatutory double patenting

Claims 17 and 19-22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,656,695. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-16 of U.S. Patent No. 6,656,695 are encompassed by the scope of claims 17 and 19-22 of the instant application.

Provisional nonstatutory double patenting

Claims 17 and 19-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7, 9, 10, 14, 33, 34, and 35 of copending Application No.10/220,999. Although the conflicting claims are not identical, they are not patentably distinct from each other because copending claims 1, 7, 9, 10, 14, 33, 34, and 35 are directed to identifying a mechanism of action of a biologically active agent on a cell in cell culture which reads on claims 17 and 19-21 of the instant claims directed to the analysis of candidate compounds for biological activity of interest.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karlheinz R. Skowronek whose telephone number is (571) 272-9047. The examiner can normally be reached on Mon-Fri 8:00am-5:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karlheinz R. Skowronek/
KRS

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

